



## NUCLEAR REGULATORY COMMISSION

10 CFR Part 35

NRC-2022-0218

RIN 3150-AK91

### Reporting Nuclear Medicine Injection Extravasations as Medical Events

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Preliminary proposed rule language; notice of availability and public meeting.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is making available preliminary proposed rule language for a rulemaking on the reporting of nuclear medicine injection extravasations as medical events. To inform this rulemaking, the NRC is posing questions to obtain input from stakeholders. The NRC will consider feedback on this notice in the development of a proposed rulemaking planned for publication in late 2024. The NRC will also hold a public meeting during the comment period on this notice to facilitate feedback.

**DATES:** Submit comments by **[INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received before this date. The public meeting will be held on May 24, 2023, from 1:00 p.m. and 4:00 p.m. eastern time (ET) via the Microsoft Teams online interface.

**ADDRESSES:** You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- **Federal Rulemaking Website:** Go to <https://www.regulations.gov> and search for Docket ID NRC-2022-0218. Address questions about NRC dockets to Dawn Forder; telephone: 301-415-3407; email: [Dawn.Forder@nrc.gov](mailto:Dawn.Forder@nrc.gov). For technical questions contact the individuals listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **Email comments to:** [Rulemaking.Comments@nrc.gov](mailto:Rulemaking.Comments@nrc.gov). If you do not receive an automatic email reply confirming receipt, then contact us at 301-415-1677.

- **Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.

For additional direction on obtaining information and submitting comments, see “Obtaining Information and Submitting Comments” in the SUPPLEMENTARY INFORMATION section of this document.

**FOR FURTHER INFORMATION CONTACT:** Irene Wu, telephone: 301-415-1951, email: [Irene.Wu@nrc.gov](mailto:Irene.Wu@nrc.gov); and Daniel DiMarco, telephone: 301-415-3303, email: [Daniel.Dimarco@nrc.gov](mailto:Daniel.Dimarco@nrc.gov). Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

## **SUPPLEMENTARY INFORMATION:**

### **I. Obtaining Information and Submitting Comments**

#### **A. Obtaining Information**

Please refer to Docket ID NRC-2022-0218 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- **Federal Rulemaking Website:** Go to <https://www.regulations.gov> and search for Docket ID NRC-2022-0218.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the "Availability of Documents" section.

- **NRC's PDR:** You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to [PDR.Resource@nrc.gov](mailto:PDR.Resource@nrc.gov) or call 1-800-397-4209 or 301-415-4737, between 8:00 a.m. and 4:00 p.m. ET, Monday through Friday, except Federal holidays.

## B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (<https://www.regulations.gov>). Please include Docket ID 2022-0218 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <https://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

## **II. Background**

### **A. Petition for Rulemaking (PRM-35-22)**

On May 18, 2020, Lucerno Dynamics, LLC (Lucerno) submitted a petition for rulemaking (PRM), PRM-35-22, that requested the NRC amend part 35 of title 10 of the *Code of Federal Regulations* (10 CFR), “Medical Use of Byproduct Material.” Lucerno proposed to require medical event reporting of radiopharmaceutical extravasations that lead to an irradiation resulting in a localized dose equivalent exceeding 50 rem (0.5 Sieverts). Extravasation is the infiltration of injected fluid into the tissue surrounding a vein or artery. Extravasation is not limited to the administration of radiopharmaceuticals. The NRC docketed the petition, and on September 15, 2020, the NRC published a notice of docketing and request for public comment in the *Federal Register* (85 FR 57148). The NRC received 488 comment submissions from the medical community, Agreement States, Congressional representatives, and members of the public and used the comments to inform the NRC staff’s recommendation to the Commission.

On May 9, 2022, the NRC staff submitted SECY-22-0043, “Petition for Rulemaking and Rulemaking Plan on Reporting Nuclear Medicine Injection Extravasations as Medical Events (Docket IDs PRM-35-22; NRC-2020-0141),” to the Commission requesting approval to consider PRM-35-22 in the rulemaking process. In staff requirements memorandum (SRM) SRM-SECY-22-0043, dated December 12, 2022, the Commission approved the staff’s recommendation to amend 10 CFR part 35

to include certain nuclear medicine injection extravasations as reportable medical events. On December 30, 2022, the NRC published a document in the *Federal Register* (87 FR 80474) stating that the NRC would consider the issues raised in the petition in the rulemaking process and closed the petition docket.

#### B. Existing Regulatory Framework for Medical Events

In 1980, the NRC amended the medical use regulations in 10 CFR part 35 to require the reporting of medical misadministrations (45 FR 31701; May 14, 1980). The reporting and analysis of medical events helps to identify deficiencies in the safe use of radioactive material and helps ensure that corrective actions are taken to prevent recurrence. In the 1980 rulemaking, the NRC stated in a comment response that it did not consider extravasation to be a misadministration because extravasation frequently occurs in otherwise normal intravenous or intraarterial injections and that extravasations are virtually impossible to avoid.

The reporting requirements were updated in 1991 (56 FR 34104; July 25, 1991), in 2002 (67 FR 20250; April 24, 2002), and again in 2018 (83 FR 33046; July 16, 2018). In 2002, the term and criteria for “misadministration” were replaced with “medical event” and several changes were made to § 35.3045, “Report and notification of a medical event.” None of these updates addressed extravasations.

### **III. Regulatory Objectives**

The NRC is planning rulemaking to amend the NRC’s regulations in 10 CFR part 35, “Medical Use of Byproduct Material” to include requirements for medical event reporting of certain extravasations that require medical attention for a suspected radiation injury. The information obtained from the medical event reporting of these extravasations would enhance the tracking and trending of these events and promote sharing information on their occurrence, detection, mitigation, and possible preventive

strategies. The planned rulemaking would affect medical licensees who administer intravenous radiopharmaceuticals for diagnostic and therapeutic purposes.

#### **IV. Specific Considerations**

The NRC is seeking feedback from the public on preliminary proposed rule language before proceeding to the development of a proposed rule. The preliminary proposed rule language is available in ADAMS at Accession No. ML23083B332 and on the federal rulemaking website at <http://www.regulations.gov> under Docket ID NRC-2022-0218. This preliminary proposed rule language does not represent a final NRC staff position, nor has it been reviewed by the Commission. Therefore, the preliminary proposed rule language may undergo significant revision during the rulemaking process.

The NRC is interested in receiving feedback and supporting rationale from the public on any aspect of the preliminary proposed rule language. Additionally, the NRC is seeking feedback on questions in the following three specific areas: Definitions, Procedures, and Healthcare Inequities. Please provide the rationale for responses to questions in these areas.

##### **Definitions**

Currently, terms such as “*Extravasation*,” “*Suspected radiation injury*,” and “*Medical attention*” are not included in § 35.2, “Definitions.” The NRC is considering adding these terms as new definitions to § 35.2 in support of adding new requirements in § 35.42, “Procedures for evaluating and reporting extravasations”; § 35.2042, “Records for procedures for evaluating and reporting extravasations”; and paragraph (a)(3) in § 35.3045, “Report and notification of a medical event,” for medical event reporting of extravasations that require medical attention for a suspected radiation injury.

1. What term should the NRC use (e.g., extravasation, infiltration) when describing the leakage of radiopharmaceuticals from a blood vessel or artery into the surrounding tissue?
2. What criteria should the NRC use to define “suspected radiation injury”?
3. What techniques or methods should be included in the definition of “medical attention”?

## **Procedures**

The NRC is exploring approaches that would reduce the reliance on patient reporting of adverse tissue reactions to an authorized user physician. One of the strategies that the NRC is considering is requiring that licensees develop, implement, and maintain written procedures to detect and report extravasations in a timely manner to the NRC.

The NRC is considering adding two new sections, § 35.42, “Procedures for evaluating and reporting extravasations,” which would require licensees to develop procedures to address all extravasations that result in a suspected radiation injury that requires medical attention from all radiopharmaceutical injections, not just from those requiring a written directive, and § 35.2042, which would add recordkeeping requirements for new § 35.42. The NRC has the following questions on these potential regulations:

4. What steps could the licensee take to minimize the chance of a radiopharmaceutical extravasation occurring?
5. What steps should the licensee take when an extravasation is suspected or discovered?
6. What techniques, technologies, or procedures (e.g., post-treatment imaging, visual observation, patient feedback) should be used to help identify an extravasation during or immediately after a radiopharmaceutical injection?

7. What techniques, technologies, or procedures (e.g., post-treatment imaging, survey measurement) should be used to better characterize an extravasation after radiopharmaceutical treatment?

8. What information should licensees provide to nuclear medicine patients on how to identify an extravasation and how to follow up with their physician if they suspect a radiation injury?

9. When should a reportable extravasation be counted as “discovered” for the purposes of notification (e.g., when medical attention is administered, when the physician identifies that the injury is from radiation)?

10. The NRC requires that licensees notify the referring physician and the individual who is the subject of a medical event no later than 24 hours after discovery of the medical event. When should licensees be required to provide notification of an extravasation medical event to the referring physician and the individual?

11. Who (e.g., patient’s primary physician, authorized user, nuclear medicine technician) should be able to identify an extravasation that could result in a “suspected radiation injury”?

12. What topics should the NRC include in guidance to assist licensees to accurately identify, characterize, and report extravasation events in a timely manner?

### **Healthcare Inequities**

The NRC is trying to better understand concerns raised by several patient safety groups regarding the higher rates of extravasation in patients of color and underserved communities. The NRC has the following questions:

13. What regulatory actions could help ensure that extravasations in patients affected by healthcare inequities are accurately assessed and reported?



14. Are vascular access tools and other technologies (e.g., ultrasound guided vein finders) likely to reduce the potential for an extravasation in all patients, particularly in patients of color?

The NRC will provide an opportunity for public comment on the proposed rule, expected to be published in late 2024. Feedback received in response to this request will be considered in the proposed rule.

## **V. Public Meeting**

The NRC will conduct a public meeting to provide information to facilitate stakeholder feedback on the preliminary proposed rule language and questions included in this document. The public meeting will be held on May 24, 2023, from 1:00 p.m. and 4:00 p.m. ET on the Microsoft Teams online platform. The NRC will publish a notice of the meeting with the meeting link and agenda on the NRC's public meeting website at least 10 calendar days before the meeting. Stakeholders should monitor the NRC's public meeting website for information about the public meeting at: <https://www.nrc.gov/public-involve/public-meetings/index.cfm>.

## **VI. Cumulative Effects of Regulation**

The NRC is following its Cumulative Effects of Regulation (CER) process by engaging with external stakeholders throughout the rulemaking process and is providing opportunity for public comment at this pre-rulemaking stage.

1. Given current or projected CER challenges, how should the NRC provide sufficient time to implement the new proposed requirements, including changes to programs and procedures?

2. If CER challenges currently exist or are expected, what should be done to address them?
3. What other (NRC or other agency) regulatory actions (e.g., orders, generic communications, license amendment requests, inspection findings of a generic nature) influence the implementation of the proposed rule's requirements?
4. What are the unintended consequences, and how should they be addressed?

## **VII. Plain Writing**

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, "Plain Language in Government Writing," published June 10, 1998 (63 FR 31885). The NRC requests comment on this document with respect to the clarity and effectiveness of the language used.

## **VIII. Availability of Documents**

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

<b>DOCUMENT</b>	<b>ADAMS ACCESSION NO. / WEB LINK / FEDERAL REGISTER CITATION</b>
Letter from Ronald K. Lattanze on behalf of Lucerno Dynamics, LLC regarding petition for rulemaking, dated May 18, 2020	ML20157A266
Notice of Docketing and Request for Comment on Petition for Rulemaking, Reporting Nuclear Medicine Injection Extravasations as Medical Events, September 15, 2020	85 FR 57148
Notice of Consideration in the Rulemaking Process for Petition for Rulemaking, Reporting Nuclear Medicine Injection Extravasations as Medical Events, December 30, 2022	87 FR 80474

SECY-22-0043, "Petition for Rulemaking and Rulemaking Plan on Reporting Nuclear Medicine Injection Extravasations as Medical Events (PRM-35-22; NRC-2020-0141)," dated May 9, 2022	ML21268A005 (package)
SRM-SECY-22-0043, "Staff Requirements – SECY-22-0043 – Petition for Rulemaking and Rulemaking Plan on Reporting Nuclear Medicine Injection Extravasations as Medical Events (PRM-35-22; NRC-2020-0141)," dated December 12, 2022	ML22346A112 (package)
Final Rule, Misadministration Reporting Requirements, May 14, 1980	45 FR 31701
Final Rule, Quality Management Program and Misadministrations, July 25, 1991	56 FR 34104
Final Rule, Medical Use of Byproduct Material, April 24, 2002	67 FR 20250
Final Rule, Medical Use of Byproduct Material—Medical Events; Definitions and Training and Experience, July 16, 2018	83 FR 33046
Preliminary Proposed Rule Language, 10 CFR Part 35	ML23083B332

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at <https://www.regulations.gov> under Docket ID **NRC-2022-0218**. In addition, the Federal rulemaking website allows members of the public to receive alerts when changes or additions occur in a docket folder. To subscribe take the following steps: 1) navigate to the docket folder (NRC-2022-0218); 2) click the "Subscribe" link; and 3) enter an email address and click on the "Subscribe" link.

## IX. Rulemaking Process

During the rulemaking process, the NRC will solicit comments from the public and will consider all comments before issuing a final rule. If the NRC does not issue a proposed rule, the NRC will issue a document in the *Federal Register* that considers feedback received on the preliminary proposed rule language and explains why the petitioner's requested rulemaking changes were not adopted by the NRC.

Dated: April 14, 2023.

For the Nuclear Regulatory Commission.

Tara Inverso,  
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Environmental, and Financial Support,  
Office of Nuclear Material Safety and Safeguards.

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